



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20205



Aquasearch Inc.
Kona Production Facility
73-4460 Queen Kaahumanu Highway
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Tel: (808)326-9301 Fax: (808)326-9401
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E-mail: aqse@aquasearch.com

December 6, 1999

Re: New Dietary Supplement Notification for The Astafactor™, softgels, 5-mg.

Dear Administrator,

Pursuant to rule 21 CFP Subpart B 190.6, please be advised of this New Dietary Supplement Notification for a new dietary supplement: The Astafactor™, softgels, 5-mg, formulated with the new dietary ingredient *Haematococcus* algal meal, for which Aquasearch is sending to FDA a separate New Dietary Ingredient Notification.

We plan to market The Astafactor™, softgels, 5 mg, as a new human dietary supplement, 75 days after the acknowledgement of receipt of this notice, unless otherwise instructed by your agency.

Please find enclosed one original and two copies of this notification.

The Astafactor™ softgels will be formulated with *Haematococcus* algal meal produced with Aquasearch's proprietary technology. The algal meal will be processed into softgels and packaged into opaque plastic bottles and/or blister packs with state-of-the-art encapsulation and packaging equipment for nutraceutical and pharmaceutical applications. The product will be stabilized with an approved food-grade natural antioxidant.

The product will be marketed by:
Aquasearch, Inc.
73-4460 Queen Kaahumanu Hwy., #110,
Kailua-Kona, Hawaii 96740,
Tel: (808) 326 – 9301, Fax: (808) 326 – 9401

Information on the origin, manufacturing process and specifications, as well as proposed labelling and usage recommendations are attached in Section 4.

The recommended daily serving size is 5 mg astaxanthin.

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There has been already significant information made public to support the safety of astaxanthin and of *Haematococcus* as a dietary supplement (see Section 5 for details), including a New Dietary Ingredient Notification for *Haematococcus* algae, from Cyanotech Corporation, submitted to FDA on March 18, 1999. In addition, antioxidant properties of astaxanthin and its metabolic effects have been widely investigated (see section 6 for details) and results from these studies give no reason to believe that there should be any safety concern when astaxanthin is ingested at the recommended levels (see Section 5 for details). We feel however that our unique proprietary production technology and the well documented safety studies conducted on our product (Section 5), provide unique additional information to confirm that algal astaxanthin and more broadly *Haematococcus* produced with Aquasearch's technology is safe when used as an ingredient for dietary supplements according to our usage recommendations.

We contend that the algal meal used in these softgels is a natural product which is unadulterated and meets the evidence of safety under the Federal Food, Drug and Cosmetic Act se. 413 (350b)(a)(2). All other ingredients are approved ingredients for dietary supplements.

Furthermore the product is produced under strict quality control and according to current food GMP recommendations, with quality checks throughout manufacturing and after processing.

Thank you very much in advance for the attention that you will give to our notification. If you have any question, do not hesitate contacting us at (808)326-9301.

Sincerely yours,


Martin Guérin
V.P. Marketing & Sales
Aquasearch Inc.

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